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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/543,489	04/06/2000	Pericles Calias	G0651/7023 WGG	7399
21005	7590	07/30/2004	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			BADIO, BARBARA P	
		ART UNIT	PAPER NUMBER	
		1616		

DATE MAILED: 07/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	09/543,489	
Examiner	CALIAS ET AL.	
Barbara P. Badio, Ph.D.	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,9-30,46-72,74 and 75 is/are pending in the application.
 - 4a) Of the above claim(s) 3,9,10,22-30 and 46-71 is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1,2,4,11-21,72,74 and 75 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ____.

First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 1, 2004 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

3. Claims 1-4, 9-30, 46-72, 74 and 75 are pending in the present application. Claims 3, 9, 10, 22-30 and 46-71 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 1, 2, 4, 11-21, 72, 74 and 75 will be examined to the extent they read on the elected species (i.e., compositions comprising EDU).

Note: Claims 9 and 10 stand withdrawn from further consideration because they do not encompass applicant's elected species, EDU wherein X is $-(CH_2)_3-$.

Claim Rejections - 35 USC § 112**4. The rejection of claims 1, 4 and 11-21 under 35 USC 112, first paragraph is maintained.**

Applicant argues the present specification provides support for the recitation that G₂ is neutral and reference is made to page 25, lines 33-34 and to claim 2 as originally filed. Applicant's argument was considered but not persuasive for the following reasons.

First, the recitation of G₂ as -CN (R₁R₂) or -N (R₁R₂) does not find support in the present specification since said groups are not discussed therein (see page 2, lines 34-35).

In response to the applicant's argument, it is noted that in defining the claimed genus of compounds on page 7, lines 20-21, the present disclosure states that "G₂ is a group having a ***net charge***" and on lines 28-29, that "Z is a ***charged species***". There is no recitation in the present specification of G₂ having a neutral charge as recited by the instant claims.

Applicant reference to page 25, lines 33-34 and originally filed claim 2 reciting a single species for support is noted. However, the disclosure of a single species in the present specification does not provide support for a genus as recited by the instant claims (see MPEP § 2163.05 (I)). In regards to the disclosure on page 25 of a "pharmaceutical composition that may be administered per se (neat) or in the form of a pharmaceutically acceptable salt", the examiner notes that the combination of G₂ and Z would result in the production of a neutral compound which may be a salt of said genus of

compounds. However, said disclosure does not provide support for the recitation of G2 having a neutral charge.

For these reasons and those given in previous Office Actions, the rejection of claims 1, 4 and 11-21 under 35 USC 112, first paragraph is maintained.

5. The rejection of claims 9 and 10 under 35 USC 112, first paragraph is withdrawn.

See reason given above in #3.

Claim Rejections - 35 USC § 102

6. The rejection of claim 1 under 35 USC 102(b) over Ito et al. ('151) is maintained.

Applicant argues the term “pharmaceutically acceptable carrier” should be interpreted in light of the present disclosure and, thus, should be read to exclude water that is not sterile. Applicant’s argument was considered but not persuasive for the following reason.

Although, the claims are read in light of the disclosure, limitations disclosed in the specification are not read into the claims. Thus, when the instant claims are read as broadly as possible, they would encompass compositions that are not sterile. In addition, there is no reason to believe that the prior art did not utilize sterile water because the skilled artisan would have the reasonable expectation that Ito would want to eliminate any factor(s) that would affect the results obtained.

For this reason and those given in previous Office Actions, the rejection of claim 1 under 35 USC 102(b) over Ito et al. ('151) is maintained.

7. The rejection of claims 9 and 10 under 35 USC 102(b) over Ito et al. ('151) is withdrawn.

See reason given above in #3.

8. The rejection of claims 72 and 75 under 35 USC 102(b) over Ito et al. ('151) is withdrawn.

9. The rejection of claim 1 under 35 USC 102(b) over Beuvery et al. ('151) is maintained.

Applicant argues EDU in the prior art is always present in combination with the Meningococcal group C polysaccharide-tetanus toxoid conjugate that is a vaccine and, thus, not a member of the recited list in Claim 1. Applicant also argues the reference does not teach a pharmaceutical utility for EDU.

Applicant's argument was considered but not persuasive for the following reasons.

Claim 1 recites a "pharmaceutical composition **comprising...**". The use of the transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps (see MPEP 2111.03). Thus, the claimed invention does not eliminate the composition of EDU and a vaccine as taught by Beuvery.

Applicant also argues the reference does not teach a pharmaceutical utility for EDU although it determines its mutagenic potential. However, the issue is not whether the reference teaches a pharmaceutical utility for EDU. The issue is whether the reference makes obvious a composition comprising EDU. The examiner's position is that the composition taught by the reference is encompassed by the instant claims.

For these reasons and those given in previous Office Actions, the rejection of claim 1 under 35 USC 102(b) over Beuvery et al. is maintained.

10. The rejection of claims 9 and 10 under 35 USC 102(b) over Beuvery et al. ('151) is withdrawn.

See reason given above in #3.

11. The rejection of claims 72 and 75 under 35 USC 102(b) over Beuvery et al. ('151) is withdrawn.

Claim Rejections - 35 USC § 103

12. The rejection of claims 1, 2, 4, 11-21, 72, 74 and 75 under 35 USC 103(a) over Beuvery et al. is maintained.

Applicant's argument and the examiner's response are as discussed above in #8.

In regards to claims 2 and 72, applicant argues the reference provides no reason to prepare a solid or aerosol pharmaceutical composition of EDU without

the toxoid conjugate. As discussed above #8, the claimed invention does not exclude the composition taught by the reference.

In addition, the addition of a carrier or solvent to an unpatentable compound has been held unpatentable. See *Ex parte Douros*, 163 USPQ 667. Therefore, the preparation of a solid, aerosol and/or sustained release composition of EDU is *prima facie* obvious based on the knowledge in the art of how to make said formulations.

For this reason and those given in previous Office Actions, the rejection of claims 1, 2, 4, 11-21, 72, 74 and 75 under 35 USC 103(a) over Beuvery et al. is maintained.

13. The rejection of claims 9 and 10 under 35 USC 103(a) over Beuvery et al. ('151) is withdrawn.

See reason given above in #3.

14. Claims 1, 2, 4, 11-21, 72, 74 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. ('151).

Ito et al. teach a genus of amino derivatives such as 1-ethyl-3-(3-dimethylaminopropyl)urea and their use in suppressing non-specific reactions in immunoassays (see col. 3, lines 7-50; figure 5, compound #1; col. 6, example 1; col. 10, claim 6).

The instant claims differ from the reference by encompassing compositions not exemplified by the reference. However, addition of a carrier or

solvent to an unpatentable compound is *prima facie* obvious. See *Ex parte Douros*, 163 USPQ 667. In addition, formulation of different preparations is well within the level of skill of the ordinary artisan.

Telephone Inquiry

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Radio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

Art Unit: 1616

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB

July 29, 2004